

In re Application of: Pilon, Aprile et al.  
Serial No.: 09/835,784  
Filed: April 13, 2001

**Remarks**

Claims 6-7, 13-14, 23-24, 31-32, 42-43, 51-52, 60-61, 69-70, 78-79, 89-90, 98-99, 107-108, 116-117, 123-124, 126-127, 129-130, 132-133, 135-136 and 138-139 are currently pending. Applicants have amended the specification and submitted a sequence listing on diskette. Applicants have also amended claims 7, 14, 24, 32, 43, 52, 61, 70, 79, 90, 99, 108, 117, 124, 127, 130, 133, 135-136, and 139 and added new claims 185-222.

**Specification Objections:**

Applicants thank the Examiner for pointing out certain typographical issues relating to the sequence identification. Applicants have amended the specification to provide SEQ ID NOS and have included the sequence for native human uteroglobin as disclosed in U.S. Application Serial No. 09/087,210, filed May 28, 1998, the disclosure of which has been previously incorporated by reference. No new matter has been added by way of the aforementioned amendments.

**35 U.S.C. §120 Priority:**

The subject matter of 6-7, 13-14, 23-24, 31-32, 42-43, 51-52, 60-61, 69-70, 78-79, 89-90, 98-99, 107-108, 116-117, 123-124, 126-127, 129-130, 132-133, 135-136 and 138-139 has been assigned an effective filing date of 04/13/2001. Applicants respectfully traverse the Examiner's assessment of the effective filing date under 35 U.S.C. §120.

As requested by the Examiner, applicants note that the subject matter of the above mentioned claims is disclosed, for example, in the parent applications listed in the following table:

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CLAIM	CITATION TO SPECIFICATION
Claim 6	<i>See e.g.</i> 09/120,264 at pp. 16, 23-24, 43, Fig. 11  <i>See e.g.</i> 09/549,926 at pp. 6-7
Claim 7	<i>See e.g.</i> 09/549,926 at pp. 7-8, 15.
Claim 13	<i>See e.g.</i> 09/120,264 at pp. 23-24, 43, Fig. 11
Claim 14	<i>See e.g.</i> 09/549,926 at pp. 7-8, 15.
Claim 23	<i>See e.g.</i> 09/549,926 at pp. 6-7, 15, 20
Claim 24	<i>See e.g.</i> 09/549,926 at pp. 7-8, 15.
Claim 31	<i>See e.g.</i> 09/549,926 at pp. 5, 9-10, 16-18, 20, 31-33, 40-46.
Claim 32	<i>See e.g.</i> 09/549,926 at pp. 7-8, 15.
Claim 42	<i>See e.g.</i> 09/549,926 at pp. 5, 8-9, 15, 20, 46.
Claim 43	<i>See e.g.</i> 09/549,926 at pp. 7-8, 15.
Claim 51	<i>See e.g.</i> 09/549,926 at pp. 5, 8-9, 15, 20, 46.
Claim 52	<i>See e.g.</i> 09/549,926 at pp. 7-8, 15.
Claim 60	<i>See e.g.</i> 09/549,926 at pp. 5, 8-9, 15, 20, 46-48.
Claim 61	<i>See e.g.</i> 09/549,926 at pp. 7-8, 15.
Claim 69	<i>See e.g.</i> 09/549,926 at pp. 5, 8-9, 15, 20, 46-48.
Claim 70	<i>See e.g.</i> 09/549,926 at pp. 7-8, 15.
Claim 78	<i>See e.g.</i> 09/549,926 at pp. 5, 8-9, 15, 20, 46-48.
Claim 79	<i>See e.g.</i> 09/549,926 at pp. 7-8, 15.
Claim 89	<i>See e.g.</i> 09/549,926 at pp. 14-18, 20, 34-36
Claim 90	<i>See e.g.</i> 09/549,926 at pp. 7-8, 15.

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Claim 98	<i>See e.g.</i> 09/549,926 at pp. 14-18, 20, 34-36
Claim 99	<i>See e.g.</i> 09/549,926 at pp. 7-8, 15.
Claim 107	<i>See e.g.</i> 09/549,926 at pp. 14-18, 20, 34-36
Claim 108	<i>See e.g.</i> 09/549,926 at pp. 7-8, 15.
Claim 116	<i>See e.g.</i> 09/549,926 at pp. 14-18, 20, 34-36
Claim 117	<i>See e.g.</i> 09/549,926 at pp. 7-8, 15.
Claim 123	<i>See e.g.</i> 09/549,926 at pp. 5, 9-10, 16-18, 20 31-32, 40-46
Claim 124	<i>See e.g.</i> 09/549,926 at pp. 7-8, 15.
Claim 126	<i>See e.g.</i> 09/549,926 at pp. 5, 9-10, 16-18, 20 31-33, 40-46
Claim 127	<i>See e.g.</i> 09/549,926 at pp. 7-8, 15.
Claim 129	<i>See e.g.</i> 09/549,926 at pp. 5, 9-10, 16-18, 20, 31-33, 40-46
Claim 130	<i>See e.g.</i> 09/549,926 at pp. 7-8, 15.
Claim 132	<i>See e.g.</i> 09/549,926 at pp. 5, 9-10, 16-18, 20, 31-32, 40-46
Claim 133	<i>See e.g.</i> 09/549,926 at pp. 7-8, 15.
Claim 135	<i>See e.g.</i> 09/549,926 at pp. 5, 9-10, 16-18, 20, 31-33, 40-46
Claim 136	<i>See e.g.</i> 09/549,926 at pp. 7-8, 15.
Claim 138	<i>See e.g.</i> 09/549,926 at pp. 5, 9-10, 16-18, 20, 31-33, 40-46
Claim 139	<i>See e.g.</i> 09/549,926 at pp. 7-8, 15.

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**35 U.S.C. §102(a or b) and (e)**

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Applicants first note that Pilon was published in November of 2000, well after the filing date of the applications cited in applicants' response to the Examiner's 35 U.S.C. §120 priority assessment.

Applicants maintain that neither Zhang nor Patierno discloses a composition comprising recombinant human uteroglobin in an amount sufficient to inhibit LPS-dependent inflammatory processes, to decrease TNF-alpha concentrations, to regulate the nitric oxide pathway, or to regulate vascular permeability and a pharmaceutically acceptable carrier or diluent. Applicants also maintain that neither Zhang nor Patierno discloses a composition comprising recombinant human uteroglobin, alone, or with fibronectin or a fragment derived from fibronectin, in amounts sufficient to suppress proliferation of CD71-positive cells, to suppress activation of CD71-positive cells, to enhance proliferation of CD11b-positive cells, to enhance activation of CD11b-positive cells, to suppress migration of vascular endothelial cells, to inhibit angiogenesis, or to inhibit extracellular matrix invasion by vascular endothelial cells.

Applicants also submit that neither Zhang nor Patierno discloses a composition comprising recombinant human uteroglobin consisting essentially of SEQ ID NO. 1 in an

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amount sufficient to inhibit LPS-dependent inflammatory processes, to decrease TNF-alpha concentrations, to regulate the nitric oxide pathway, or to regulate vascular permeability and a pharmaceutically acceptable carrier or diluent as claimed in new claims 185 - 192. Applicants also submit that neither Zhang nor Patierno discloses a composition comprising recombinant human uteroglobin consisting essentially of SEQ ID NO. 1, alone, or with fibronectin or a fragment derived from fibronectin, in amounts sufficient to suppress proliferation of CD71-positive cells, to suppress activation of CD71-positive cells, to enhance proliferation of CD11b-positive cells, to enhance activation of CD11b-positive cells, to suppress migration of vascular endothelial cells, to inhibit angiogenesis, or to inhibit extracellular matrix invasion by vascular endothelial cells as claimed in new claims 193 - 222.

**35 U.S.C. §103**

Claims 129, 130, 132, 138, and 139 have been rejected as obvious over Zhang, as evidenced by Pilon and Cummins.

Applicants respectfully note that Pilon was published in November of 2000, well after the filing date of the applications cited in applicants' response to the Examiner's 35 U.S.C. §120 priority assessment.

Applicants maintain that Zhang, alone or in combination with Pilon and Cummins, does not disclose, teach or suggest a composition comprising recombinant human uteroglobin in an amount sufficient to inhibit extracellular matrix invasion by vascular endothelial cells in a patient, and a pharmaceutically acceptable carrier or diluent. Applicants further maintain that Zhang, alone or in combination with Pilon and Cummins, does not disclose, teach or suggest a composition comprising recombinant human uteroglobin, alone, or with fibronectin or a

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fragment derived from fibronectin, in amounts sufficient to suppress migration of vascular endothelial cells, to inhibit angiogenesis, or to inhibit extracellular matrix invasion by vascular endothelial cells and with a pharmaceutically acceptable carrier of diluent.

**35 U.S.C. §112**

The currently pending claims have been rejected as indefinite under 35 U.S.C. §112. Applicants respectfully traverse the §112 rejections.

With respect to the phrase “in an amount sufficient to extracellular matrix invasion” of claim 135, applicants have amended claim 135 to read in relevant part “in an amount sufficient to inhibit extracellular matrix invasion.” Applicants thank the examiner for pointing out the typographical error.

With respect to the term “kg” in claims 7, 14, 24, 32, 43, 52, 61, 70, 79, 90, 99, 108, 117, 124, 127, 130, 133, 136, and 139, applicants have amended these claims to clarify the object which possesses the property of kg by reciting “of body mass”.

With respect to claims 129, 130, 132, 133, 138, and 139 applicants maintain that fragment derived from fibronectin is clearly defined in applicants’ specification at e.g. pages 46-50 and 50-53.

With respect to the term “recombinant human uteroglobin” in the above listed currently pending claims, applicants respectfully maintain that one skilled in the art would be able to determine whether a particular amino acid sequence fell within the definition set forth in the claims by easily comparing it to the known amino acid sequence of native human uteroglobin in light of the percentage identity disclosed in the specification at page 17. Having done so one

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skilled in the art would immediately be aware of whether a particular sequence was or was not definitive of recombinant human uteroglobin.

No fee, other than the fee for a three-month extension, is believed to be necessary in connection with the filing of this Response. The Director is hereby authorized to charge such fee(s), and any additional fees deemed necessary, to Deposit Account No. 50-0540.

Respectfully submitted,

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